K093706

510(k) SUMMARY

SUBMITTER:	Hybridyne Imaging Technologies, Inc.
CONTACT PERSON:	Terrence Lall
DATE PREPARED:	October 30, 2009
DEVICE TRADE NAME:	ProxiScan™
COMMON NAME:	Handheld Gamma Camera
CLASSIFICATION NAME:	Gamma Camera (21 CFR 892.1100 Product Code: IYX)
PREDICATE DEVICE(S):	Anzai Medical Company, Ltd. Anzai eZScope AN Portable Gamma Camera (K022342) and the Siemens Medical Solutions USA, Inc EC9-4 Ultrasound Transducer (K060879)
DEVICE DESCRIPTION:	The ProxiScan™ is an imaging device consisting of the imaging system: detector module, high-voltage power supply and computer. The detector module and high-voltage power supply are integrated into a small handheld enclosure, which works in conjunction with an external low-voltage power supply and a computer for data acquisition and processing.

INDICATION FOR USE:

The ProxiScan™ is indicated for use in imaging the distribution of radionuclides in the human body using planar imaging techniques. ProxiScan™ may also be used intraoperatively, on pathological specimens and for endocavity applications if a protective sheath is used.

TECHNOLOGICAL CHARACTERISTICS:

The ProxiScan™ is an imaging device consisting of the imaging system: detector module, high-voltage power supply and computer. The detector module and high-voltage power supply are integrated into a small handheld enclosure, which works in conjunction with an external low-voltage power supply and a computer for data acquisition and processing. Signals from CZT detectors are transferred frame-by-frame to the display computer. A software program in the computer reads the data and displays the images.

NON CLINICAL TEST RESULTS:

Appropriate performance testing was performed. All specifications were met. It was also tested in accordance with the requirements of the IEC-60601-1 for electrical safety and in accordance with the ISO-10993 standard for biocompatibility.

FUNCTIONAL TEST RESULTS:

ProxiScan™ was subjected to functional testing including system energy linearity, intrinsic energy resolution, spatial resolution, contrast evaluation, uniformity, count rate characteristics and sensitivity. All specifications were met.

CONCLUSIONS:

This pre-market notification has demonstrated Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(i)(1) of the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

APR - 2 2010

Hybridyne Imaging Technologies, Inc.
% Mr. Barry S. Sall, RAC
Principal Consultant
PAREXEL Consulting
195 West Street
WALTHAM MA 02451

Re: K093706
Trade/Device Name: ProxiScan™
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) camera
Regulatory Class: II
Product Code: IYX
Dated: March 8, 2010
Received: March 9, 2010

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093706

Device Name: ProxiScan™

Indications for Use:

The ProxiScan™ is indicated for use in imaging the distribution of radionuclides in the human body using planar imaging techniques. ProxiScan™ may also be used intraoperatively, on pathological specimens and for endocavity applications if a protective sheath is used.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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